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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TILAK M. SHAH

Appeal 2009-002203
Application 10/815,282
Technology Center 1700

Before EDWARD C. KIMLIN, PETER F. KRATZ, and
JEFFREY T. SMITH, *Administrative Patent Judges*.

KRATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 74-108. We have jurisdiction pursuant to 35 U.S.C. § 6.

Appellant's claimed invention is directed to a gastric occlusive device comprising a balloon (gas retentive device) and an inflation element. The device provides for inflation of the balloon within a subject's gastric cavity. The balloon is constructed via vacuum thermoformed half sections of multi-layer films, which half-sections are bonded to each other along peripheral portions forming a seam. The balloon exhibits a non-pillowed, spheroidal shape upon inflation. In this regard, pillowing is said to be contraindicated for such a gastric occlusive device (App. Br. 6).

Claim 74 is illustrative and reproduced below:

74. A gastric occlusive device comprising:
 a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from two vacuum thermoformed half-sections of a multilayer film comprising: (A) a layer of sealing film, having main top and bottom surfaces; and (B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character, wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and
 an inflation element adapted to permit inflation of the balloon within the gastric cavity of a subject for treatment of said subject.

The Examiner relies on the following prior art reference as evidence in rejecting the appealed claims:

Connors	6,976,950 B2	Dec. 20, 2005
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Claims 74-108 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Connors.

We reverse for substantially the reasons set forth by Appellants taken in light of the testimony of Tilak M. Shaw as set forth in the Declaration under 37 C.F.R. § 1.132 (Decl.) (App. Br. 5-14, Evid. Appdx.; Reply Br. 1-6). We add the following for emphasis.

All of the appealed claims require a gastric occlusive device comprising a balloon that includes a seam (formed from bonded vacuum thermoformed half-sections comprising multi-layer films) with the balloon being so constructed as to have a spheroidal and non-pillowed shape upon inflation.

Connors is directed to an implantable device that is disclosed as being useful in baffling or attenuating transient pressure waves in organs of the body, such as in the human urinary bladder for treating urinary tract disorders (col. 1, ll. 15-34 and col. 10, l. 47- col. 13, l. 28). Connors furnishes several illustrative embodiments which are disclosed as being related to the fields of urology and gynecology, albeit Connors notes that embodiments of the invention may be useful in other organs of the body (col. 6, ll. 48-62).

The Examiner generally focuses on separate embodiments depicted in Figures 5 and 16C of Connors in maintaining the rejection (Ans. 3-4). The Examiner relies on Figure 5 of Connors for disclosing an attenuation device including a spherically configured inflatable container made from first and second compartments bonded together by a seam.

Appellant urges that the attenuation device of the embodiment of Figure 5 of Connors is pillowed as evidenced by Figure 5A of Connors, not non-pillowed as required by the claims on appeal (App. Br. 10-11).

The Examiner turns to Figure 16C of Connors for an alleged teaching of a spherically-shaped balloon that is non-pillowed and to selections from column 23 of Connors for a teaching of employing a multi-layer wall structure comprising a gas barrier layer and a moisture barrier layer (Ans. 5). In this regard, the Examiner maintains that “it would have been obvious to one of ordinary skill in the art to have employed the multilayer’s in the embodiment of Fig. 16[C] in the balloon of Fig. 5 [of Connors], for the purpose of enhancing flexibility, moisture barrier, gas barrier, and high impact strength” (Ans. 5).

However, Figure 16C of Connors does not show a seam as being present as required by the appealed claims for the balloon prepared from vacuum thermoformed half-sections as urged by Appellant (Reply Br. 3). Appellant argues that the Examiner has not reasonably carried the burden to establish how Figure 16C of Connors coupled with general references to a spherical shaped attenuation device in the disclosure of Connors, among the other disclosed shapes and embodiments therein, would have suggested a gastric occlusive device balloon structure that is not only spherical and non-pillowed, but also includes a seam formed from bonding separate multi-layer film halves, as claimed by Appellant (App. Br. 7-14; Reply Br.2-6).

In this regard, Appellant has buttressed the arguments presented with evidence in the form of a Declaration under 37 C.F.R. § 1.132 by Tilak M. Shaw (the named inventor). Mr. Shaw opines that vacuum thermoforming is the only method of forming a device corresponding to the claimed device known to Mr. Shaw and Connors does not disclose vacuum thermoforming as a method for making a multilayer film-formed balloon via separately formed halves, which balloon includes a peripheral bonding seam joining the

halves and is non-pillowed and spheroidal in shape in the inflated state (Decl. 7-15; *see generally* App. Br. and Reply Br.). Moreover, according to Mr. Shaw, one of ordinary skill in the art would not have looked to vacuum thermoforming at the time of the invention for forming such a balloon (Decl. 13-14).

As argued by Appellant, the Examiner has not specifically articulated in the Answer how Connors otherwise discloses or suggests to one of ordinary skill in the art how to construct a balloon with all of the characteristics required by each of the appealed claims (Reply Br. 2-6).

On this record, the Examiner's failure to address and attempt to discredit the 37 C.F.R. § 1.132 Declaration testimony of Tilak M. Shaw employed in support of Appellant's arguments in the Appeal Brief and Reply Brief, of itself, warrants reversal of the stated rejection.

In sum and as correctly urged by Appellants, the Examiner does not reasonably explain how the referred to Patent Specification passages of Connors taken with the depicted embodiments represented in Figures 5 and 16C teach or suggest a balloon having all of the claimed characteristics to an ordinary skilled artisan given the additional non-rebutted information provided in the 37 C.F.R. § 1.132 Declaration testimony of Tilak M. Shaw (App. Br. 7-14, Evid. Appdx.; Reply Br. 1-6).

The aforementioned failure on the part of the Examiner represents a dispositive issue that we resolve in Appellant's favor.

ORDER

The Examiner's decision to reject claims 74-108 under 35 U.S.C. § 103(a) as being unpatentable over Connors is reversed.

Appeal 2009-002203
Application 10/815,282

REVERSED

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